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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,450	12/30/2003	Richard L. Boyd	286336.150US1/NOR-011CP2	2366

7590 08/25/2005  
Shann Kerner, Ph.D.  
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60 State Street  
Boston, MA 02109

EXAMINER
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BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/748,450	Applicant(s) BOYD, RICHARD L.	
	Examiner Michail A. Belyavskyi	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 15-23, 25-33, 35-60, 63-68 and 72-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 15-23, 25-33, 35-60, 63-68 and 72-76 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's amendment, filed 08/13/04 is acknowledged.

Claims 15-23, 25-33, 35-60, 63-68 and 72-76 are pending.

### ***Restriction Requirement***

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 16-23 and 25-29 drawn to a method for improving an immune response to a vaccine antigen in a patient, wherein the thymus of the patient has been at least in part atrophied, classified in Class 424, subclasses 184.1 and 577.
  - II. Claims 30-33, 35-37, drawn to a method for improving an immune response to a vaccine antigen in a patient, wherein the method of disrupting sex steroid mediated signaling to the thymus is through surgical castration, classified in Class 119, subclass 174.
  - III. Claims 30-33, 35, 36 and 38 drawn to a method for improving an immune response to a vaccine antigen in a patient, wherein the method of disrupting sex steroid mediated signaling to the thymus is through chemical castration, classified in Class 424, subclasses 184.1.
  - IV. Claims 30-33, 35, 36, 39-42, and 76 drawn to a method for improving an immune response to a vaccine antigen in a patient, wherein the method of disrupting sex steroid mediated signaling to the thymus is through administration of one or more pharmaceutical, classified in Class 424, subclasses 184.1 and 577.
  - V. Claims 30-33, 35, 36 and 74 drawn to a method for improving an immune response to a vaccine antigen in a patient, wherein sex steroid mediated signaling to the thymus is disrupted by lowering the level of sex steroid hormones, classified in Class 424, subclasses 184.1 and 577.
  - VI. Claim 72 drawn to a method for enhancing transplantation of donor hematopoietic stem cells into thymus of a recipient, classified in Class 424, subclasses 184.1 and 577.
  - VII. Claim 73 drawn to a method for increasing virus-specific peripheral T cell responsiveness of a patient, classified in Class 424, subclass 184.1.

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Claims 15 and 43-60,63-68 and 75 link inventions of Groups I-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 15 and 43-69. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Groups I- VII are different methods. These inventions are different with respect to ingredients, method steps, and endpoints which require non-coextensive searches ; therefore, each method is patentably distinct.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### Species Election

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

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5. In any one of the Group I- V is elected, applicant is required to elect a specific method for improving a patient's immune response wherein : (i) a specific of vaccine antigen is selected from the group recited in claim 45; (ii) a specific vaccine is selected from the group recited in claim 63; (iii) specific cytokine is selected from the group recited in claim 67; (iv) specific growth factor is selected from the group recited in claim 68 or 69.

These species are distinct because the methods for improving a patient's immune response wherein (i) a specific of vaccine antigen is selected from the group recited in claim 45; (ii) a specific vaccine is selected from the group recited in claim 63; (iii) specific cytokine is selected from the group recited in claim 67; (iv) specific growth factor is selected from the group recited in claim 68 or 69 differ with respect to the use of specific vaccine antigen, specific vaccine, specific cytokine and specific growth factor ; thus each specific method employing a of specific vaccine antigen, specific vaccine, specific cytokine and specific growth factor represents patentably distinct subject matter. Furthermore, the examination of (i) a specific of vaccine antigen is selected from the group recited in claim 45; (ii) a specific vaccine is selected from the group recited in claim 63; (iii) specific cytokine is selected from the group recited in claim 67; (iv) specific growth factor is selected from the group recited in claim 68 or 69 in the method for improving a patient's immune response would require different searches in the scientific literature.

**In addition, if applicant elects Group IV, then applicant is required to elect from the following as well:**

6. If Group IV is elected, applicant is further required to elect: (i) a specific method for improving a patient's immune response wherein specific pharmaceutical is, for example, selected from the Groups recited in Claims 40 or 41 or 42.

These species are distinct because the methods for improving a patient's immune response wherein specific pharmaceutical is, for example, selected from the Groups recited in 40 or 41 or 42 differ with respect to the use of specific pharmaceutical; thus each specific method employing a specific pharmaceutical represents patentably distinct subject matter. Furthermore, the examination of specific pharmaceutical such as ones recited in the Claims 40 or 41 or 42 in the method for improving a patient's immune response would require different searches in the scientific literature.

Applicant is advised that a response to this requirement **must include an identification of the species that is elected** consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the

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election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed.

A telephone call was made to Ann-Louise Kerner on 08/12/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 22, 2005

